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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,622	BACHYNSKY ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-14 and 55-63* is/are pending in the application.

4a) Of the above claim(s) *55 and 56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-14,57 and 59* is/are rejected.

7)☒ Claim(s) *58,60-63* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-5, 7-14 and 55-63 are presented for examination.

Applicant's amendment filed September 12, 2005 has been received and entered into the application. Accordingly, the specification at pages 1, 4, 12, 18, 19, 25 and 90 and claims 1 and 5 are amended, claims 6 and 15-54 are cancelled and claims 55-63 are newly added.

Please note that a letter from Nicholas Bachynsky was filed July 12, 2005 and was received by the Office and placed of record in the application. The document has been considered as part of the response. Since Applicant has appointed an attorney or agent of record to conduct all business before the U.S. Patent and Trademark Office, no further correspondence with Nicholas Bachynsky has been made. Double correspondence with an Applicant and Applicant's attorney or agent will not be undertaken. See 37 C.F.R. 1.33.

It is further noted that Applicant has erroneously requested to amend the specification at page 18, lines 19-20 with the paragraph set forth at page 2 of the present amendment. However, such a paragraph is found at page 17. Applicant is required to properly identify the page and line numbers of the paragraph(s) to be amended in any subsequent submission to the Office.

In view of the amendments and accompanying remarks, the objections to the specification as set forth at pages 3-5 of the previous Office Action dated April 11, 2005 have each been hereby **withdrawn**.

In view of the cancellation of claims 6 and 15-54, the objection to claim 54 and rejection of claims 6 and 54 under 35 U.S.C. 112, first paragraph, or under 35 U.S.C. 102(b) as set forth at pages 5-10 and 12-16 of the previous Office Action dated April 11, 2005 have each been hereby rendered **moot**.

Subject Matter of Newly Added Claims 55-56 Withdrawn

Applicant's amendment to add new claims 55-56 has been carefully considered in light of the subject matter that was elected and examined in the previous first non-final office action.

The MPEP states at §819:

"The general policy of the Office is not to permit the Applicant to shift to claiming another invention after an election is once made and action given on the elected subject matter."

Newly submitted claims 55-56 are directed to species of the elected invention that are independent and patentably distinct from the invention originally claimed for the following reasons: newly added claims 55-56 are drawn to multiple patentably distinct species of disease or disorder for which the induced intracellular hyperthermia is intended for diagnosis or treatment.

The species recited in newly added claims 55-56 are considered patentably distinct from one another because the newly added claims are drawn to a variety of disparate diseases and disorders, wherein each is practiced in a unique population of subjects (i.e., a population of patients afflicted with atherosclerosis versus a population of patients afflicted with cancer). Each of the species of diseases or disorders is sufficiently dissimilar in function such that distinctly different end results are produced (i.e., patients with atherosclerosis treated by the presented claimed active agent would experience amelioration of artery blockage, whereas patients with cancer would experience inhibition of cancerous cellular proliferation and a reduction in the risk of metastatic spread). The distinct nature of the species is further supported by the fact that each disease has a different and distinct etiology and pathophysiological manifestations, and that each is differently treated. Such is sufficient to indicate that each disease listed above is differently

searched in the patent and non-patent literature and that a search for one disease will not necessarily result in a comprehensive search of any one or more of the other diseases listed. Notwithstanding that Applicant may have established an underlying commonality for the claimed diseases or disorders, it remains that each of the diseases are recognized in the art as being clinically and pathophysiologically distinct from one another and, thus, each of the species is patentably distinct from any one or more of the others.

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 55-56 are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. 1.142(b) and MPEP §821.03.

Objection to the Claims (New Ground of Objection)

Claims 55, 58-59, 61-63 are objected to for reciting "used to diagnosis or treat" in claim 55 or "used to treat or diagnosis" in claims 58-59 and 61-63. The recitation of the word "diagnosis" is grammatically improper and should properly read "diagnose". Appropriate correction is required.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 7-14 and 59 are rejected under 35 U.S.C. 112, first paragraph, for being enabling for the treatment of Non-Hodgkin's lymphoma, prostate carcinoma, glioblastoma multiforme or Kaposi's sarcoma (see the present specification at page 14, lines 31-34), infections that result from Borrelia burgdorferi, Mycobacterium leprae, Treponema pallidum, HIV, hepatitis C, herpes virus or papillomavirus (see the present specification at page 14, line 34-page 15, line 2), or infestations that result from Candida, Sporothrix schenkii, Histoplasma, Paracoccidiodes, Aspergillus, Leishmania, malaria, acanthomoeba or cestodes (see the present specification at page 15, lines 2-4), but fail to reasonably provide enablement for the treatment of malignancies or cancer in general, infections in general or infestations in general as is encompassed in present claims 5 and 7, for the reasons already made of record at pages 5-10 of the previous Office Action dated April 11, 2005.

Cancellation of claim 6 has rendered the present rejection under 35 U.S.C. 112, first paragraph, moot as applied to such a claim.

Newly added claim 59 is properly included in the present rejection because the claim is drawn to the use of induced intracellular hyperthermia for the treatment of diagnosis of carcinoma, which is interpreted to encompass carcinomas in general.

Applicant's remarks at pages 14-16 of the amendment filed September 12, 2005 have been carefully considered, but fail to be persuasive in establishing error in the propriety of the present rejection.

Applicant states that the first paragraph of 35 U.S.C. 112 requires nothing more than objective enablement and that the PTO bears the initial burden in rejecting a claim under 35 U.S.C. 112 to set forth "a reasonable explanation as to why it believes that the scope of

protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application." Applicant submits that the Cecil reference is not relevant and merely provides an overview for cancer treatment and known therapies to treat infestations or infections. Applicant further submits that it is not the function of the claims to exclude possible inoperative substances and that 35 U.S.C. 112 simply requires that there be sufficient disclosure to teach those of ordinary skill in the relevant art how to make and use the invention as broadly as it is claimed. Applicant remarks that the scope of enablement must only bear a "reasonable correlation" to the scope of the claims and that time-consuming experimentation is acceptable if such experimentation is standard in the art and the artisan is given sufficient direction or guidance.

In response to Applicant's statement that the PTO bears the initial burden in rejecting a claim under 35 U.S.C. 112, Applicant is again directed to pages 5-10 of the previous Office Action dated April 11, 2005. *In re Marzocchi et al.,* 169 USPQ 367 (CCPA 1971) is again relied upon:

"[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with the enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contained therein which must be relied on for enabling support*; assuming that sufficient reasons for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in the specification is truly enabling." (emphasis added).

The terms "infections" or "infestations" or "malignancies" or "cancer" as recited in the present claims is considered to be inclusive of all "infections" or "infestations" or "malignancies" or "cancers" known in the art. That is, in order to be enabled to practice the present invention, the skilled artisan would have to accept that by administering the presently claimed active agent(s) all known types of infection, infestation or cancer could be effectively treated and there would be reasonable guarantee that all such types of cancer would be amenable to such treatment. Such a situation is sufficiently unusual that data would need to be shown in order to establish that any type of cancer could be effectively treated through the administration of the claimed active agents. Because absolute success is not reasonably possible with the treatment of most diseases or disorders, especially a condition as highly complex as cancer, the specification, which lacks an objective showing that all such types could be treated, is viewed as lacking an enabling disclosure of the same.

While Applicant asserts that the Cecil reference is not relevant, such an argument is not a point well taken because it is *unquestionably* relevant to showing the state of the art with regard to the wide variety of pharmacologic and surgical therapies known in the art for the treatment of a plethora of cancers, infections or infestations. Furthermore, in the absence of any evidence or persuasive argument as to why the citation of such a reference bears no weight on propriety of the present rejection, such an argument has not been further considered.

Applicant's statement that the Cecil reference merely provides an overview for cancer treatment and known therapies to treat infestations or infections is not disputed. The reference was cited specifically for the succinct summary of pharmacologic therapies known and commonly used in the art for the treatment of cancers, infections or infestations contained

therein. Citations of comprehensive and copious literature discussing, in significant detail, every known type of cancer, infection or infestation and the variety of pharmacologic and non-pharmacologic (i.e., surgical) therapies known in the relevant art are not required to demonstrate that a claimed invention lacks sufficient enablement under 35 U.S.C. 112, first paragraph. Rather, sufficient support must be provided to show that the presently claimed situation (i.e., that the presently claimed active agent is capable of treating cancer, infections or infestations *in general*) would not have been reasonably expected by one of ordinary skill in the art because the concept of a single agent, or even a combination of agents, that was known to be effective to treat all known types of cancer, infections or infestations would have been unique and, thus, met with a great deal of skepticism and would not have been accepted by the skilled artisan on its face.

Applicant's argument that it is not a function of the claims to exclude possible inoperative substances is not relevant to the present rejection. The rejection does not ask to exclude inoperative substances. Rather, it casts doubt on Applicant's assertion that the presently claimed active agent is capable of treating all known types of cancer, infections or infestations, given the knowledge generally available to one of ordinary skill in the art at the time of the invention.

As asserted at pages 5-10 of the previous Office Action dated April 11, 2005, the Cecil reference demonstrates the complexity of the treatment of cancers, infections or infestations, such that the skilled artisan would not have been imbued with at least a reasonable expectation of success that one single agent would have shown efficacy in the treatment of all cancer types, all infection types and all infestation types. For example, as can be seen in the cited portions of

Cecil, the disparate nature of cancers, such as liquid hematopoietic cancers or solid cancers or the aggressiveness of certain cancers or the inability to treat certain organ cancers, wherein the organ is required to maintain normal function of the body (i.e., brain cancer), does not lend itself to arriving at a reasonable conclusion that one single agent, whether it be Applicant's claimed agent or even any other agent known to man, is capable of treating all known types of cancers.

The same reasoning applies to infections or infestations, but for the difference in the type of disorder.

In light of what Applicant has disclosed, which amounts merely to an assertion that the presently claimed agent is capable of treating all known types of cancer, infection or infestation, it remains that the present application lacks sufficient disclosure to teach those of ordinary skill in the relevant art how to make and use the invention for the treatment of cancer, infection or infestation in general.

It is again acknowledged that the present disclosure specifically and adequately supports the treatment of Non-Hodgkin's lymphoma, prostate carcinoma, breast carcinoma, glioblastoma multiforme, glioma and Kaposi's sarcoma; infections resulting from Borrelia burgdorferi, Mycobacterium leprae, Treponema pallidum, HIV, hepatitis C, herpes virus or papillomavirus, or infestations resulting from Candida, Sporothrix schenkii, Histoplasma, Paracoccidiodes, Aspergillus, Leishmania, malaria, acanthomoeba or cestodes, but does not provide reasonable support for the treatment of cancers, infections or infestations in general.

It is further noted that the greater the degree of unpredictability and/or complexity of the state of the art with regard to particular disease states or conditions, the more comprehensive and substantial the teachings and disclosure must be to support such an invention since such an

invention would be claiming an outcome that would not have been reasonably expected by the skilled artisan. It is acknowledged that Applicant is not required to enable each and every single embodiment encompassed by the claims, but must enable a sufficient number to be reasonably representative of that which is claimed. In this regard, Applicant's statement that the scope of enablement must only bear a "reasonable correlation" to the scope of the claims is not disputed.

However, Applicant has not provided any evidence or persuasive argument in the present disclosure or in the response to the rejection made under 35 U.S.C. 112, first paragraph, as to how the examples and data shown in the specification is reasonably representative of the treatment of cancer ***in general***, infections ***in general***, or infestations ***in general***. In consideration of the fact that the specification fails to provide sufficient reasoning or support for why the data demonstrated in the disclosure would be logically extrapolated to the treatment of such conditions in general and, further, in light of the fact that the state of the art with regard to the treatment of such conditions is highly complex and poorly understood, it remains that the specification is viewed as lacking an enabling disclosure of the presently claimed subject matter of claims 5, 7-14 and 59.

Moreover, Applicant's remark that time-consuming experimentation is acceptable if such experimentation is standard in the art and the artisan is given sufficient direction or guidance has been considered, but it remains that the present disclosure fails to provide sufficient direction or guidance for the presently claimed subject matter for the reasons already made of record above.

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 14 remain rejected under 35 U.S.C. 112, first paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention, for the reasons already made of record as set forth at pages 10-11 of the previous Office Action dated April 11, 2005.

Applicant's remarks at page 17 of the amendment filed September 12, 2005 have been carefully considered, but fail to be persuasive in establishing error in the propriety of the present rejection.

Applicant submits that the specification at pages 63-67 describes how to synthesize novel derivatives and analogs and that one of skill in the art would be able to determine the scope of the claims when the claims are read in light of the specification.

Applicant's remarks and the specification at pages 63-67 have been carefully considered, but fail to adequately delineate the scope of the compounds intended by the use of the term "analog" or "derivative". Applicant's reliance on the specification to define such terms has been considered, but it is noted that the specification merely exemplifies compounds that may be construed as analogs or derivatives of the dinitrophenol compound presently claimed. Such exemplification and explanation fails to present a limiting definition such that the skilled artisan would have been reasonably apprised of the metes and bounds of the claim(s).

In light of such, claims 13 and 14 fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-14, 57-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Rubin (U.S. Patent No. 4,481,195; 1984), already of record, for the reasons already made of record as set forth at pages 12-16 of the previous Office Action dated April 11, 2005.

Cancellation of claims 6 and 54 has rendered the present rejection under 35 U.S.C. 102(b) moot as applied to such a claim.

Newly added claims 58-60 are properly included in the present rejection because the claim is drawn to the use of induced intracellular hyperthermia for the treatment of diagnosis of breast carcinoma, which is expressly taught by Rubin (see col.1, lines 18-23; col.2, lines 30-51; and col.7, lines 34-40). The recitation of "wherein the induced intracellular hyperthermia enhances the immune system of the subject" in newly added claim 57 has been considered, but amounts to no more than a recitation of the resultant function of the method and fails to impart any patentable moment to the present claims. Given that the same active agent is being administered to the same subject via the same method, it is proper to conclude that the method disclosed by Rubin also exerts an immune enhancing function as is presently claimed.

Applicant's remarks at page 17 of the amendment filed September 12, 2005 have been carefully considered, but fail to be persuasive in establishing error in the propriety of the present rejection.

Applicant submits that the present amendments to independent claim 1 to now read upon whole body hyperthermia is not similar to local hyperthermia and Rubin, therefore, does not anticipate independent claim 1 and its dependent claims.

Applicant's attention is drawn to Rubin at column 3, lines 34-49, which states:

"Other steps for increasing beta-glucuronidase activity at the tumor cells may also be undertaken. One method of doing this is to elevate the temperature of the toxic cells at the time of treatment. **This may be done by elevating the temperature of the entire body such as by use of a pyrogenic drug**...Known pyrogenic drugs include etiocholanolone, progesterone, **dinitrophenol**, dinitrocresol, etc." (emphasis added)

Rubin, therefore, directly anticipates the subject matter of claim 1.

While Applicant relies upon Rubin at column 3, lines 57-60, where the reference states, "Local hyperthermia in the region of suspected tumor cells is preferred to general hyperthermia because general hyperthermia will also increase the beta-glucuronidase activity in healthy cells", reliance on such passages is merely indicative of a preferred embodiment of the invention. Despite the fact that local hyperthermia using the disclosed active agents may have been preferable to general hypertheremia (i.e., whole body hyperthermia), such does constitute a teaching away from the broader disclosure of the reference as a whole. Moreover, while it may be construed that local hyperthermia may represent a non-preferred embodiment, the teachings of a reference are not limited to only that which is preferred.

Regarding non-preferred embodiments the MPEP states at §2123, "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including non-preferred embodiments...**Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments**." (emphasis added) Thus, although Rubin discloses that local hyperthermia in the region of suspected tumor cells may be preferable to general hyperthermia of the entire body, such does not teach away from the broader disclosure of compositions in the reference, namely wherein general hyperthermia is induced.

Further Rejection of Newly Added Claims 58 and 60-63 Not Made

In light of the present rejection that has been made and maintained under 35 U.S.C. 112, first paragraph, regarding the treatment of cancers, infections or infestations in general, the Examiner would be in error to conclude that the treatment of the various specific types of cancers, infections or infestations that are recited in newly added claims 58 and 60-63 would have been obvious to the skilled artisan in light of the teaching of Rubin, who discloses a method of treating breast or bronchogenic cancers, lymphoma or streptococci, staphylococci or E. coli infections using the hyperthermic method described in the reference. As already discussed above, the state of the art with regard to such conditions is highly unpredictable and/or complex, such that the efficacy demonstrated in the treatment of one type of cancer, infection or infestation would not reasonably suggest, or properly be extrapolated to include, the treatment of any type of cancer, infection or infestation known in the art. For this reason, an obviousness rejection

under 35 U.S.C. 103(a) has not been made over the subject matter of newly added claims 58 and 60-63.

Conclusion

Rejection of claims 1-5, 7-14, 57 and 59 remains proper and is **maintained**.

Claims 55-56 have been withdrawn from consideration.

Claims 58 and 60-63 are objected to for the reasons of record above.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

November 23, 2005

RAYMOND HENLEY III
PRIMARY EXAMINER
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